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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier A. Corbin

Anti-Infective Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Anti-Infective Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 10, 2002, from 8:30 a.m. to 5 p.m., and on July 11, 2002, from 8:30 a.m. to 4 p.m.

Location: Marriott Washingtonian Center, Grand Ballroom, 9751 Washingtonian Blvd., Gaithersburg, MD.

Contact Person: Tara P. Turner, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, e-mail: TurnerT@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12530. Please call the Information Line for up-to-date information on this meeting.

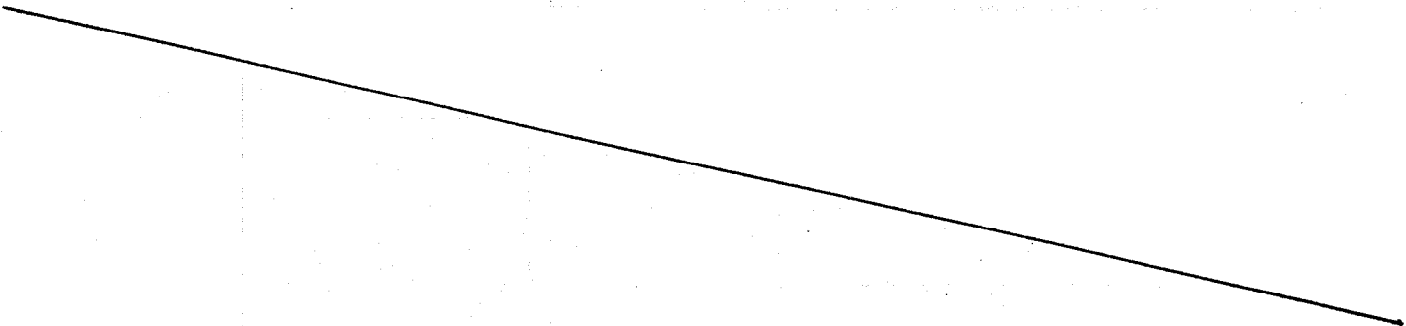
Agenda: On July 10, 2002, the committee will discuss the new drug application (NDA) 21-242, artesunate rectal capsules, World Health Organization, proposed for emergency treatment of acute malaria in patients who cannot take oral medication and for whom parenteral treatment is not available. On July 11, 2002, the committee will discuss clinical trial design for studies of otitis media. Since the publication of the 1998 "Draft Guidance to Industry on Acute Otitis Media—

Developing Antimicrobial Drugs for Treatment” (see the FDA Internet Web site at <http://www.fda.gov/cder/guidance/>), the agency has received advice from the public and the Anti-Infective Drugs Advisory Committee on changes to clinical trial design (see transcripts from November 19, 1997; July 29 to 31, 1998; January 30, 2001; and November 7, 2001, for various antimicrobials at the FDA Internet Web site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>). The agency has compiled these comments into a plan for further discussion by the committee.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 2, 2002. Oral presentations from the public will be scheduled between approximately 1 p.m. and 1:30 p.m. on July 10, 2002, and between approximately 1 p.m. and 2 p.m. on July 11, 2002. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 2, 2002, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA’s advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

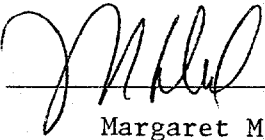
FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Tara Turner at least 7 days in advance of the meeting.



Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: 6/17/02
June 17, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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